UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF WASHINGTON

NICOLE WILSON, DAWN DAUGHDRILL, AND TERESA WINDERS	*	CIVIL ACTION:
Plaintiffs,	*	
VERSUS	*	
KAISER FOUNDATION HOSPITALS, INC GREG ADAMS, ANDREW BINDMAN, MD	*	
Defendants,	*	

* * * * * * * * * * * * *

COMPLAINT
(JURY TRIAL REQUESTED)

Now into court, through undersigned counsel, come Plaintiffs, Nicole Wilson, Dawn Daughdrill, and Teresa Winders, (hereinafter "Plaintiffs"), who file this Complaint against Defendants, Kaiser Foundation Hospitals, Greg Adams, CEO of Kaiser Foundation Hospitals, Inc., Andrew Bindman MD, CMO of Kaiser Foundation Hospitals (hereinafter collectively referenced as "Kaiser") presenting allegations and causes of action as follows:

I. Introduction

1. This action arises out of Kaiser Permanente, a state actor when performing on behalf of Washington State under the State-run CDC COVID-19 Vaccination CDC Program ("CDC Program") and when acting pursuant to a State-enforced custom discussed *infra*, establishing and enforcing a policy, requiring Plaintiffs to inject federally owned investigational new drugs ("INDs") into their bodies under threat of penalty, thus mandating that Plaintiffs surrender their Fourteenth Amendment rights guaranteed to them by the federal government and Washington under the CDC Program.

2. The Fourteenth Amendment guarantees Plaintiffs the right to (1) enjoy the benefits of a federal program (a property right), (2) exercise statutory entitlements (a property right), (3) refuse public disclosure of their private health and identifiable information (right to privacy), (4) refuse to become human subjects under federally funded research activities (right to bodily autonomy and integrity), and (5) refuse unwanted investigational drugs and unwanted medical treatments (right to bodily autonomy and integrity), without incurring a penalty or losing a benefit to which they are otherwise entitled.

3. Plaintiffs are currently and/or formerly licensed as healthcare workers by the State and former employees of Kaiser.

4. On August 27, 2021, Kaiser issued a new company policy ("IND Mandate") requiring individuals (e.g., employees, volunteers, contractors, and vendors) to inject federally funded investigational drugs offered exclusively under the CDC Program into their bodies or obtain an exemption as a condition of engaging in economic or other activities with it.

5. The only drugs offered under the CDC Program were wholly owned by the federal government, FDA-classified as investigational, authorized only for emergency use, immunized from liability under the PREP Act, and subject to the legally effective informed consent doctrine.

6. Kaiser is constitutionally, statutorily, and contractually prohibited from listing a federally funded IND under a mandatory requirement.

7. The mandatory use of the drugs offered under the CDC Program violates Plaintiffs' fundamental right to refuse unwanted investigational drugs and medical treatments.

8. The IND Mandate, and enforcement thereof, violated Plaintiffs' fundamental rights guaranteed to them by the Fourteenth Amendment, federal law, and the CDC Program, and their liberty interests discussed *infra*.

9. The IND Mandate and enforcement thereof is the direct and proximate cause of Plaintiffs' injuries.

10. Plaintiffs bring this suit as a civil rights action under the United States Constitution, 42 U.S.C. §1983, and Washington common law seeking monetary damages.

II. JURISDICTION AND VENUE

10. This Court has original jurisdiction under 28 U.S.C. §§1331 and 1343.

11. The civil rights portions of this action raise federal questions under the Spending Clause and the Fourteenth Amendment to the U.S. Constitution.

12. This Court has original jurisdiction under 42 U.S.C. §§1983 and 1988.

13. This Court has the authority to award costs and reasonable attorney's fees under 42 U.S.C. §1988.

14. This court has supplemental jurisdiction over Plaintiffs' state law claims.

15. This Court has personal jurisdiction over Kaiser as it is domiciled within this Court's jurisdictional boundaries.

16. This Court has subject matter jurisdiction over the parties because all acts complained of herein were committed by Kaiser in the State of Washington and caused damage and/or deprivation to the Plaintiffs listed herein.

17. Venue is proper in this court because all events underlying the claims in this Complaint occurred in the State of Washington, which is situated within this Court's jurisdiction, and all Defendants reside in the State of Washington.

III. PLAINTIFFS

18. The following individuals are plaintiffs herein:

19. Plaintiff Nicole Wilson is an adult individual who, at all times pertinent, resided in the State of Washington and was previously an employee of Kaiser in Washington.

20. Plaintiff Dawn Daughdrill is an adult individual who, at all times pertinent, resided in the State of Washington and was previously an employee of Kaiser in Washington.

21. Plaintiff Teresa Winders is an adult individual who, at all times pertinent, resided in the State of Washington and was previously an employee of Kaiser in Washington.

IV. DEFENDANTS

22. The following are named as defendants herein:

23. Defendant, Kaiser Foundation Hospitals, is a non-profit, public-benefit corporation formed according to the laws of the State of California and headquartered in Oakland, California. It operates 39 hospitals and more than 700 medical offices, with over 300,000 personnel, including over 87,000 physicians and nurses nationwide. Kaiser is licensed to do business in Washington State.

24. Defendant, Greg Adams, was at all times pertinent, the Chief Executive Officer and PolicyMaker of Kaiser Foundation Hospitals and was aware and responsible for duties owed to Plaintiffs under the CDC COVID-19 Vaccination Program Provider Agreement, and the organization's FWA, IRB. Mr. Adams is named as a defendant in his official and individual capacities.

25. Defendant, Andrew Bindman, MD, was at all times pertinent, the Chief Medical Officer and PolicyMaker of Kaiser Foundation Hospitals and was aware and responsible for duties owed to Plaintiffs under the CDC COVID-19 Vaccination Program Provider Agreement, and the organization's FWA, IRB. Dr. Bindman is named as a defendant in his official and individual capacities.

V. THE GRAVAMEN OF THE CASE

26. Plaintiffs hold the fundamental right to refuse, without penalty or pressure, unwanted federally funded investigational drugs and unwanted medical treatments, irrespective of the federal agency, department, or program offering the drugs and treatments.

27. All drugs offered through the CDC Program were FDA-classified as investigational.

28. Plaintiffs hold property rights under the CDC Program and applicable laws discussed herein to refuse the federally funded INDs, which Kaiser prospectively agreed to protect on behalf of Washington and the United States Government ("USG") under the CDC COVID-19 Vaccination Program Provider Agreement ("Provider Agreement") and the Federal Wide Assurance ("FWA") program, but Kaiser unlawfully deprived Plaintiffs of the specific property right to refuse by applying *ultra vires* penalties to that chosen option, which conduct was outside the scope of Kaiser's discretionary authority.

29. There is no legal condition under which Kaiser can mandate that Plaintiffs use an IND, EUA product, or PREP Act countermeasure, nor can Kaiser terminate an employee for refusing the drug pursuant to Washington State law and Kaiser's voluntary agreement to obtain Plaintiffs' "legally effective informed consent" on behalf of Washington and the USG, a purely governmental function under the CDC Program as well as Kaiser's Institutional Review Board ("IRB"), and FWA agreements.

VI. FACTUAL ALLEGATIONS

A. Background

30. In 2020, the federal executive branch established the CDC Program as an emergency public function to distribute and administer COVID-19 INDs to willing recipients.

31. The FDA assigns IND status when a drug manufacturer requests authorization pursuant to 21 C.F.R. §312 (Investigational New Drug Application) to administer an unlicensed drug to humans involving investigational activities. This is the first step to obtaining a Biologics License Application pursuant to 21 U.S.C. §355(a).

32. Pfizer received Investigational New Drug application number 19736 for its Pfizer-BioNTech COVID-19 Vaccine. Moderna and Janssen also received Investigational New Drug application numbers for their COVID-19 Vaccines.

33. INDs do not have a legal indication for their safety and efficacy for treating, curing, or preventing any known disease.

34. INDs are considered investigational when used in the normal course of medical practice.

35. Similarly, drugs granted an Emergency Use Authorization ("EUA") are considered investigational because EUA drugs cannot already be licensed to treat, prevent, or cure the intended emergency use. (21 U.S.C. §360bbb-3(c)(3)).

36. A drug is regulated according to its classification and labeling, not its formulation.

37. The use of INDs funded or authorized by the USG must comply with 21 U.S.C. §360bbb *et seq*. (Expanded Access to Unapproved Therapies and Diagnostics), 45 C.F.R. Part 46 (Protection of Human Subjects), the Belmont Report, 10 U.S.C. §980 (Limitation on Use of Humans as Experimental Subjects), and IRBs, when offered to humans whose private identifiable information will be known, and data collected about their use of the product will be studied to add

to the product's generalizable knowledge (45 C.F.R. Part 46), which are considered research conditions.[1]

38. The primary governmental function required of any person agreeing to act on behalf of the USG when administering an IND is to obtain an individual's legally effective informed consent as outlined under 45 C.F.R. §46.116 and the Belmont Report.

39. The legally effective informed consent principle requires the person offering an individual an IND to first establish a legally approved environment that ensures the individual is not under "coercion," "undue influence," "unjustifiable pressures," or a sanction to use the drug. There are no exceptions to this ministerial requirement.[2]

40. The unique principle of legally effective informed consent is that it places a ministerial duty upon persons acting under the USG's authority to ensure that a potential recipient is not under pressure to use the IND.

41. Legally effective informed consent is nullified whether the pressure is positive (i.e., unjustifiable monetary awards) or negative (i.e., loss of benefits).

42. The INDs mandated by Kaiser are drugs under such research and legal conditions.[3]

[1] "Federal funds administered by a Federal department or agency may not be expended for research involving human subjects unless the requirements of this policy have been satisfied." 45 CFR 46.122. The USG and persons acting on the USG's behalf as part of the CDC Program were required to adhere to the federal scheme at all times material.
[2] The National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research.– Belmont Report. Washington, DC: U.S. Department of Health and Human Services. 1979. Part C "Voluntariness"
[3] The CDC Program and each assigned EUA required the State and its recruited parties to conduct research activities on behalf of the USG, requiring adherence to 45 C.F.R. Part 46 and the Belmont Report.

43. The USG established the FWA program in 2001 to ensure that persons acting on its behalf complied with the federal scheme[4] designed to protect humans from medical research abuses resulting from the 1974 National Research Act.[5]

44. Kaiser's FWA with the USG is triggered upon Kaiser accessing federal funding, or acting under the USG's authority, when offering INDs to potential recipients.

45. Washington[6] has an active FWA and, as a result, is intimately familiar with the protocols under the regulatory scheme requiring protection of human subjects involved in federally authorized research activities, such as the CDC Program and any Emergency Use Authorization ("EUA") issued under 21 U.S.C. §360bbb-3 ("EUA Statute").

46. Kaiser has an active FWA[7] requiring it to comply with the same legal duties.

47. Pursuant to the 1974 National Research Act, the Belmont Report[8] established the legal nature of informed consent known as "legally effective informed consent" promulgated under 45 C.F.R. §46.116, making it a property right subject to the Fourteenth Amendment's Due Process Clause relating to bodily autonomy.

48. Congress clearly established a property interest for Plaintiffs, stating, "Before involving a human subject in research covered by this policy, an investigator **shall obtain** the legally effective informed consent of the subject or the subject's legally authorized representative." (45 C.F.R. §46.116(a)(1)) (emphasis added).

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[4] The FWA program requires the organization offering INDs to humans to provide the USG with a written assurance that they will comply with 45 C.F.R. Part 46 and the Belmont Report. The primary duty is to comply with 45 C.F.R. §46.116 "legally effective informed consent." The program is managed by the Office of Human Research Protections (OHRP) under the Health and Human Services (HHS) agency.
[5] H.R.7724 - National Research Act, 93rd Congress (1973-1974), See Title II
[6] FWA00000327
[7] FWA00025698
[8] The National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research.– Belmont Report. Washington, DC: U.S. Department of Health and Human Services. 1979

49. The phrase "shall obtain" means Congress has conferred upon Plaintiffs a right to give their legally effective informed consent,[9] thereby making legally effective informed consent a property right involving bodily autonomy, which the Fourth Circuit[10] and Supreme Court holds is a fundamental right and liberty interest. Specifically, the Supreme Court holds:

> "No right is held more sacred or is more carefully guarded by the common law than the right of every individual to the possession and control of his own person, free from all restraint or interference of others unless by clear and unquestionable authority of law." *Union Pacific Railway Co. v. Botsford*, 141 U.S. 250 (1891);
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> "[O]n balance, the right to self-determination ordinarily outweighs any countervailing state interests, and competent persons generally are permitted to refuse medical treatment, even at the risk of death. Most of the cases that have held otherwise, unless they involved the interest in protecting innocent third parties, have concerned the patient's competency to make a rational and considered choice" *Cruzan v. Director, Missouri Dep't of Health*, 497 U.S. 261, 273 (1990), citing In re Conroy, 98 N.J. 321, 348, 486 A.2d 1209, 1223 (N.J. Jan. 17, 1985);
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> "The right assumed in *Cruzan*, however, was not simply deduced from abstract concepts of personal autonomy. Given the common-law rule that forced medication was a battery, and the long legal tradition protecting the decision to refuse unwanted medical treatment, our assumption was entirely consistent with this Nation's history and constitutional traditions." *Washington v. Glucksberg*, 521 U.S. 702 (1997);
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> "The protections of substantive due process have for the most part been accorded to matters relating to marriage, family, procreation, and the right to bodily integrity." *Albright v. Oliver*, 510 U.S. 266, 272 (1994)

[9] "To have a property interest in a benefit, a person clearly must have more than an abstract need or desire for it. He must have more than a unilateral expectation of it. He must, instead, have a legitimate claim of entitlement to it." *Board of Regents of State Colleges v. Roth*, 408 U.S. 564 (1972). And "[p]roperty interests, of course, are not created by the Constitution. Rather, they are created, and their dimensions are defined, by existing rules or understandings that stem from an independent source such as state law -- rules or understandings that secure certain benefits and that support claims of entitlement to those benefits. Thus, the welfare recipients in *Goldberg v. Kelly*, 397 U.S. 254 (1970), had a claim of entitlement to welfare payments that was grounded in the statute defining eligibility for them." *Id.*

[10] "The right to be free of unwanted physical invasions has been recognized as an integral part of the individual's constitutional freedoms, whether termed a liberty interest protected by the Due Process Clause, or an aspect of the right to privacy contained in the notions of personal freedom which underwrote the Bill of Rights. The right to refuse medical treatment has been specifically recognized as a subject of constitutional protection." *U.S. v. Charters*, 829 F.2d 479 (4th Cir. 1987)

50. Drugs classified by the FDA as INDs do not have a legal indication to treat, prevent, or cure the disease that is the subject of the emergency and, therefore, fall under the Supreme Court's precedent involving unwanted medical treatment because the drugs are only used for investigational purposes.

51. Therefore, whenever a potential recipient is presented with an opportunity to use a federally funded IND, they have a fundamental right and liberty interest in providing or withholding legally effective informed consent.

52. Punishing individuals for refusing investigational drugs and unwanted medical treatments violates Plaintiffs' fundamental right to bodily autonomy and their property rights under the CDC Program and applicable laws, all of which guarantee that Plaintiffs will not incur a penalty or lose a benefit to which they are otherwise entitled.[11]

53. In 2020, the federal government's executive branch (the Department of Defense) purchased all COVID-19 INDs (see, *infra*) and established the CDC Program requiring recruited parties (i.e., states) to perform research activities on its behalf.

54. The USG informed Kaiser that:

> "At this time, **all COVID-19 vaccine in the United States has been purchased by the U.S. government** (USG) for administration exclusively by providers enrolled in the CDC COVID-19 Vaccination Program **and remains U.S. government property until administered to the recipient.** Only healthcare professionals enrolled through a health practice or organization as vaccination providers in the CDC COVID-19 Vaccination Program (and authorized entities engaged in shipment for the Program) are authorized to possess, distribute, deliver, administer, receive shipments of, or use USG-purchased COVID-19 vaccine. Other possession, distribution, delivery, administration, shipment receipt, or use of COVID-19 vaccine outside the parameters of the Program constitutes, at a minimum, theft under 18 U.S.C. §641 and violation of other federal civil and criminal laws.

[11] "A statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled." 45 CFR §46.116(b)(8)

> Violators are subject to prosecution to the full extent of the law." (Emphasis added)

55. The USG is under a ministerial duty to obtain an individual's legally effective informed consent when offering one of the COVID-19 INDs because those drugs and the CDC Program require Plaintiffs to become human subjects (45 CFR §46.102(e)(1)) in federally funded research activities (45 CFR §46.102(l)).[12]

56. The USG is under a ministerial duty to obtain Plaintiffs' legally effective informed consent when offering INDs because it purchased the COVID-19 INDs using DoD funding (10 USC §980).[13]

57. The USG is under a ministerial duty to inform Plaintiffs of their right to accept or refuse the drugs authorized only for emergency use under 21 U.S.C. §360bbb-3(e)(1)(A)(ii)(III).

58. The option to accept is a property right because it allows Plaintiffs to access unapproved drugs that are exempt from 21 U.S.C. §355(a) during a declared emergency. The option to refuse is a property right because it allows Plaintiffs to refuse the drugs without cost, despite a chemical, biological, radiological, nuclear, or pandemic event, specifically because the drugs are not approved for their intended emergency use.

59. The duty to inform Plaintiffs of their right to refuse means Plaintiffs have the right to refuse at all times without any additional legal conditions placed upon them by any third party. The right is a federally secured right with which no other person can interfere by requiring an individual to seek a religious or medical exemption to exercise that right.

60. To comply with its legal obligations relating to the INDs, the USG established the CDC Program in 2020, publishing guidelines under "COVID-19 Vaccination Program Interim

[12] The research activities are listed in the Provider Agreement and the "conditions of authorization" in each EUA. See Exhibit A, Provider Agreement; Exhibit B, December 11, 2020 EUA Letter; Exhibit C, August 23, 2021 EUA Letter.
[13] See Exhibit D, DoD Purchase of COVID-19 Drugs

Operational Guidance Jurisdiction Operations" ("Playbook") to help states it recruited to "operationalize a vaccination response to COVID-19 within [its] jurisdiction" and to help the State with its "COVID-19 vaccination program planning and implementation."[14]

61. The Playbook informed states that:

(1) A COVID-19 vaccination provider is any vaccination provider who has been enrolled in the COVID-19 Vaccination Program,[15]

(2) Jurisdiction/jurisdictional, as used in the Playbook document, refers to the federal immunization funding awardees described in the Executive Summary and their state public health emergency preparedness counterparts who are tasked with developing COVID-19 vaccination plans for submission to CDC,[16]

(3) To receive/administer COVID-19 vaccine, constituent products, and ancillary supplies, vaccination provider facilities/organizations must enroll in the federal COVID-19 Vaccination Program coordinated through their jurisdiction's immunization program [17] and the vaccination provider must agree to the Provider Agreement whereby they **promise** to Comply with FDA's requirements, including EUA-related requirements **described in FDA's Letter of Authorization**, as applicable. Providers **must also administer COVID-19 vaccine in compliance with all applicable state and territorial vaccine laws** (emphasis added),[18]

(4) Enrolled COVID-19 vaccination providers must be credentialed/licensed in the jurisdiction where vaccination takes place, and sign and agree to the conditions in the CDC COVID-19 Vaccination Program Provider Agreement,[19]

(5) Jurisdictions must facilitate and monitor IIS [Immunization Information System] reporting by enrolled vaccination providers,[20]

(6) State-level personnel must closely monitor activities at the local level **to ensure** the COVID-19 Vaccination Program is implemented

[14] See Exhibit E, CDC Playbook
[15] See Exhibit E, CDC Playbook, Footnote 1
[16] See Exhibit E, CDC Playbook, Footnote 2
[17] See Exhibit E, CDC Playbook, p. 21
[18] Washington incorporated the Provider Agreement as its policy when requiring each public or private party to sign and agree to the terms of the CDC Program as a condition of administering the federally owned COVID-19 drugs on the State's behalf.
[19] See Exhibit E, CDC Playbook, p. 21
[20] See Exhibit E, CDC Playbook, p. 35

throughout the jurisdiction in adherence with federal guidance and requirements,[21]

(7) **Help the public to understand key differences in FDA emergency use authorization and FDA approval** (i.e., licensure),[22] (emphasis added)

(8) Jurisdictions will be provided an opportunity to opt out of having pharmacies in their area receive direct allocations,[23]

(9) Ensure provider agreement, profile form, and redistribution agreement (if applicable) are thoroughly and accurately completed by each enrolled provider, retained on file for a minimum of 3 years, and made available to CDC upon request.[24]

62. Therefore, any state volunteering to perform for the USG is responsible for ensuring it and its recruited state actors comply with any EUA, educate the public about the legal distinctions between a licensed drug and an EUA drug, and ensure all persons it recruits signs the Provider Agreement and maintain a copy of that agreement on file for a minimum of three years.

63. The Executive Branch only recruited U.S. States and Territories because those entities have active FWAs requiring them to comply with the same legal obligations as the USG.

64. Washington agreed to perform for the USG under the CDC Program, and no entity within the State could administer the drugs without first being authorized by the State and agreeing to administer the drugs within the constitutional restraints of the Fourteenth Amendment.

65. At all times material, Washington was required to perform the governmental function of accepting Plaintiffs' legally effective informed consent anytime it, or persons acting on its behalf, presented Plaintiffs with an opportunity to use the INDs.

[21] See Exhibit E, CDC Playbook, p. 8 (emphasis added)
[22] See Exhibit E, CDC Playbook, p. 42
[23] See Exhibit E, CDC Playbook, p. 26
[24] See Exhibit E, CDC Playbook, p. 22

66. Though novel, the CDC Program is an emergency public function reserved for the state by the USG. The state was obligated to perform the USG's functions, which are traditional and exclusive government functions requiring private parties that volunteered to serve as Organizations under the CDC Program to owe constitutional obligations to individuals who are offered the federally owned INDs.

67. Under the CDC Program, the Washington Department of Health willfully assumed the role of the "Emergency Response Stakeholder"[25] under each EUA.

68. The State is legally required to (1) "identify vaccination sites to receive authorized Pfizer-BioNTech COVID-19 Vaccine **and ensure its** distribution and **administration**, **consistent** with the terms of this letter and CDC's COVID-19 Vaccination Program" and (2) "ensure that vaccination providers within their jurisdictions are aware of this letter of authorization, and the terms herein and any subsequent amendments that might be made to the letter of authorization, **instruct them about the means** through which they are **to obtain and administer the vaccine under the EUA**, and ensure that the authorized labeling [i.e., Fact Sheet for Healthcare Providers Administering Vaccine (Vaccination Providers) and Vaccine Information Fact Sheet for Recipients and Caregivers] is made available to vaccination providers through appropriate means (e.g., e-mail, website)" (emphasis added).[26]

69. Therefore, the State is under a ministerial duty to ensure the "conditions of authorization" of each EUA are lawfully implemented, including ensuring that all individuals are informed of their right to accept or refuse the EUA drug.

[25] See Exhibit C, August 23, 2021 EUA Letter, FN12, "emergency response stakeholder"
[26] See Exhibit C, August 23, 2021 EUA Letter, p. 10. "Conditions of Authorization," Letter "O"

70. The CDC Program provided Washington with the CDC COVID-19 Vaccination Program Provider Agreement ("Provider Agreement") to ensure the State complied with its legal duties when it recruited others to act on its behalf.[27]

71. Washington incorporated the Provider Agreement into official State policy and required recruited parties to sign and comply with its terms. The Agreement also required potential recipients to have the right to refuse without penalty or pressure.

72. The Provider Agreement placed duties upon the State and its recruited parties (i.e., vaccination providers), including, but not limited to:

> (1) Organization must administer COVID-19 Vaccine in accordance with all requirements and recommendations of CDC and CDC's Advisory Committee on Immunization Practices (ACIP),
>
> (2) Organization must not sell or seek reimbursement for COVID-19 Vaccine and any adjuvant, syringes, needles, or other constituent products and ancillary supplies that the federal government provides without cost to Organization,
>
> (3) Organization must administer COVID-19 Vaccine regardless of the vaccine recipient's ability to pay COVID-19 Vaccine administration fees,
>
> (4) Before administering COVID-19 Vaccine, Organization must provide an approved Emergency Use Authorization (EUA) fact sheet or vaccine information statement (VIS), as required, to each vaccine recipient, the adult caregiver accompanying the recipient, or other legal representative,[28]
>
> (5) Organization must report moderate and severe adverse events following vaccination to the Vaccine Adverse Event Reporting System (VAERS), [29]
>
> (6) Organization must comply with all applicable requirements as set forth by the U.S. Food and Drug Administration, including but not limited to requirements in **any EUA** that covers COVID-19 Vaccine (emphasis added),

[27] See Exhibit A, Provider Agreement
[28] The Fact Sheet is part of the process of obtaining an individual's legally effective informed consent.
[29] This "reporting" constitutes "research" under 45 C.F.R. Part 46 and the Belmont Report.

(7) Organization must administer COVID-19 Vaccine in compliance with all applicable state and territorial vaccination laws.[30]

73. The duties of Washington and its recruited parties include administering the CDC program lawfully, providing the "Vaccine Information Fact Sheet" (i.e., official drug label) to potential recipients, monitoring and reporting adverse events to VAERS, complying with the Provider Agreement in full, and informing all potential recipients that the drug "has not been approved or licensed by the FDA" when promoting the product to any person for any reason.[31]

74. The State agreed to conduct research activities on behalf of the USG, including to "report moderate and severe adverse events following the drug's administration to the Vaccine Adverse Event Reporting System (VAERS)," and "provide a completed COVID-19 vaccination record card to every COVID-19 Vaccine recipient, the adult caregiver accompanying the recipient, or other legal representative" by ensuring its recruited "Organizations" that signed the Provider Agreement knew how to monitor and report those adverse reactions to VAERS.[32]

75. These two required conditions extend to all of Washington's recruited parties because the USG cannot delegate the governmental function to the State and its recruited parties without delegating the USG's legal obligations.

76. The Conditions of Authorization of each EUA require each manufacturer, State health agency, and vaccination provider to obtain a person's private health information, monitor them for adverse events, research "a pre-specified list of adverse events of special interest, along with deaths and hospitalizations"[33] and report that data to the Center for Biologics and Evaluation

[30] The Provider Agreement is not only an agreement between the "Organization" and the federal government, but also an agreement between the Organization and the State since the State incorporated the Provider Agreement requirements into official State policy.
[31] See Exhibit C, 8/23/2021 EUA Letter, Sections R - Y
[32] See Exhibit A, Provider Agreement.
[33] See Exhibit C, 8/23/2021 EUA Letter, Section N

Research (CBER, an FDA department) and to the Vaccine Adverse Event Reporting System ("VAERS") to "contribute to generalizable knowledge" (45 CFR 46.102(l)) of the product.

77. The CDC Program was a federally funded program involving research activities requiring the USG to comply with 45 CFR Part 46 requirements, the Belmont Report, 10 USC §980, the FWA agreement, and the federal constitution relating to privacy and unwanted investigational medical treatment.

78. Therefore, Washington agreed to perform the ministerial function of accepting Plaintiffs' chosen option under 21 U.S.C. §360bbb-3(e)(1)(A)(ii)(III) and to obtain Plaintiffs' "legally effective informed consent" on behalf of the USG, which was also required of Washington's recruited parties.

B. Kaiser

79. Kaiser is licensed by the State of Washington.

80. At all times pertinent, Plaintiffs were employed by Kaiser.

81. At all times pertinent, Kaiser acted under color of law as a state actor under the State-run CDC Program because Washington cannot delegate its governmental functions without delegating its Fourteenth Amendment obligations.

82. Upon information and belief, Washington signed the CDC COVID-19 Vaccination Provider Agreement, agreeing to perform governmental functions for the State.

83. FWA00000327 is Washington's written assurance to the USG that it will ensure that Plaintiffs' right to refuse federally funded INDs is protected anytime they are presented with an opportunity to use the INDs, such as under Kaiser's Mandate.

84. Kaiser is an "Organization" under the Provider Agreement and is subject to its terms and conditions.

85. Kaiser is a "vaccination provider" under each EUA, and as the Organization under the Provider Agreement, it is required to inform Plaintiffs of their right to accept or refuse the INDs without penalty or pressure.

86. Kaiser had a duty under each EUA to "clearly and conspicuously [] state that: This product has not been approved or licensed by FDA, but has been authorized for emergency use by the FDA..."[34]

87. Kaiser was required to provide the CDC Program's benefits to all persons equally, free of charge, and to perform the governmental function of accepting the potential recipient's chosen option irrespective of the relationship that Kaiser had with the potential recipient.

88. Under the Provider Agreement, the CEO and CMO, or their equivalents, were required to sign and comply with the agreement and to perform the duties required by the State under the CDC Program.[35] Moreover, Kaiser had to list all persons responsible for the administration of the CDC Program on the Provider Agreement.

89. Under the Provider Agreement, Kaiser agreed to comply with "any EUA."[36]

90. On August 27, 2021, Kaiser Policymakers issued a new company policy[37] that, as applied, violated federal law, state law, and deprived Plaintiffs' of their statutory and Constitutional rights.

91. The policy stated in part:

> "Kaiser Permanente is requiring all employees be fully vaccinated for COVID-19 by September 30, 2021, or to submit proof of a qualifying medical or religious exemption. Those who are not vaccinated by September 30 will be placed on unpaid administrative leave for up to 60 days until they are fully vaccinated."

[34] Exhibit C, August 23, 2021 EUA Letter, Section "Y", p. 12.
[35] Exhibit A, Provider Agreement, p. 1.
[36] Exhibit A, Provider Agreement, p. 3, Section 12(a)
[37] Exhibit F, Kaiser Policy

> "Unvaccinated employees and those who have not provided proof of vaccination must follow workplace safety rules including routine proof of negative COVID-19 test results based on regional requirements."
>
> "Employees who are not fully vaccinated or who do not have an approved exemption will no longer be eligible to continue employment and will be terminated" by December 01, 2021.

92. The IND Mandate exclusively relied upon the federally owned COVID-19 INDs for compliance in violation of Kaiser's ministerial duties under the CDC Program.

93. Kaiser's mandate that Plaintiffs inject federally owned INDs under threat of penalty conflicted with the CDC Program, the Provider Agreement, the USG's duties, Washington's duties, and Kaiser's FWA and deprived Plaintiffs of their Fourteenth Amendment rights.

94. Kaiser's mandate that Plaintiffs inject federally owned INDs under threat of penalty deprived Plaintiffs of rights under the EUA statute, the PREP Act, the CDC Program, 45 CFR §46.116, and 10 U.S.C. §980.

95. Kaiser's mandate vitiated Plaintiffs' legally effective informed consent when Kaiser required the use of federally funded INDs under threat of penalty despite promising the USG and the State that Kaiser would never place individuals, such as Plaintiffs, under pressure to use the drugs, nor penalize Plaintiffs when they refused. The specific and sole reason Kaiser terminated Plaintiffs was for refusing to inject the federally owned INDs into their bodies.

96. Kaiser's mandate exceeded its authority under the CDC Program because Kaiser mandated the use of the drugs available under the Program but failed to inform Plaintiffs of the right to refuse without pressure or penalty and Kaiser failed to inform Plaintiffs that the drugs were not approved or licensed by the FDA.

97. Kaiser's mandate exceeded its authority under the CDC Program when it required Plaintiffs to seek a medical or religious exemption as the only means of refusing the INDs because Plaintiffs already possessed the right to refuse without penalty or pressure.

98. Kaiser exceeded its authority under the CDC Program when it required Plaintiffs to become human subjects in federally funded research activities.

99. Kaiser's mandate exceeded its authority under the CDC Program when it required Plaintiffs to involuntarily surrender their private health information to unknown persons, for unknown reasons, and for an unknown length of time, as required under the Program.

100. Kaiser's mandate deprived Plaintiffs of their fundamental right to refuse EUA/PREP Act investigational drugs and unwanted medical treatments.

101. Kaiser's mandate exceeded its authority under the CDC Program when it presented the EUA/PREP Act investigational drugs as if the FDA labeled them with a legal indication as a vaccine,[38] or for their safety and efficacy.

C. State Action.

102. Kaiser was a state actor in two ways – when it interacted with anyone regarding the drugs available under the CDC Program and when it acted in accordance with Washington's State-enforced custom of allowing penalties to be imposed on potential recipients of the EUA/PREP Act investigational drugs.

103. Washington voluntarily assumed responsibility for ensuring the implementation of the CDC Program within its jurisdiction on behalf of the USG.

[38] "A sponsor or investigator, or any person acting on behalf of a sponsor or investigator, shall not represent in a promotional context that an investigational new drug is safe or effective for the purposes for which it is under investigation or otherwise promote the drug." 21 C.F.R. §312.7

104. Washington was under a constitutional duty to obtain Plaintiffs' legally effective informed consent anytime Plaintiffs were presented with an opportunity to use one of the federally owned INDs.

105. Washington was legally obligated to ensure that all individuals were informed of their option to accept or refuse the INDs and to prevent any other person or entity from interfering with that right.

106. The CDC Program requires a person to voluntarily (1) become a human subject in federally funded research activities, (2) surrender their due process rights to bring a common law cause of action resulting from injury, (3) assume greater risks to their health and legal rights, (4) agree to the injection of investigational unlicensed drugs, (5) allow their private health information and data collected about their interaction with the drugs to be shared with unknown persons for unknown reasons for an unknown length of time.

107. Washington is constitutionally prohibited from mandating a person to (1) subject themselves to biomedical research activities, (2) surrender their Fourteenth Amendment rights to bring a cause of action should the drugs injure them, (3) assume greater risks to their health, and legal rights, (4) inject investigational drugs into their bodies, (5) allow unwarranted governmental intrusion into their private lives, as a condition of enjoying public benefits. (*Perry v. Sindermann*, 408 U.S. 593, 92 S.Ct. 2694, 33 L.Ed.2d 570 (1972).)

108. Washington could not issue a mandate requiring a person to forfeit their constitutional right to exercise their property interest under the CDC Program to refuse the INDs.

109. While Washington was not required to engage private entities to perform the federal government's function of administering federally owned EUA/PREP Act investigational drugs under the CDC Program, it chose to do so under its exclusive authority.

110. Because Washington agreed to perform the function of obtaining Plaintiffs' informed consent on behalf of the USG under the CDC Program, it was required to delegate that governmental function and its Fourteenth Amendment obligations to its recruited state actors, such as Kaiser. See *West v. Atkins*, 487 U.S. 42, 56 (1988) (state cannot avoid constitutional obligations by delegating functions to private actors).

111. Washington's responsibilities under the CDC Program, including obligations related to federally owned EUA/PREP Act investigational drugs, flowed through Washington to Kaiser via the Provider Agreement and the federal laws cited herein.

112. Therefore, under Supreme Court precedent, because Washington owed Fourteenth Amendment obligations to its citizens, it could not allow a private party to participate in the CDC Program unless Washington required that private party to administer the program in accordance with the Fourteenth Amendment.

113. Kaiser was a state actor because it agreed to, and did, engage in joint action with the State and USG and thus owed Fourteenth Amendment obligations to Plaintiffs under the CDC Program.

114. Kaiser was a state actor because it was in a symbiotic relationship with Washington, where it was under a legal obligation to ensure that persons it offered the drugs to in any form (i.e., IND Mandate) were informed of their right to accept or refuse the drugs, and was further under a legal obligation to accept the individual's chosen option, with which Kaiser had no discretionary authority to interfere.

115. Moreover, Kaiser was already under a legal duty via its FWA agreement when it promised the USG that it would never place an individual under pressure to use federally funded INDs.

116. Kaiser engaged in joint conduct with the State to help the State perform for the USG under the CDC Program, from which Kaiser had no discretionary authority to deviate.

117. Kaiser was under the State's complete control and authority anytime Kaiser engaged in any activity related to the CDC Program.

118. Therefore, Kaiser, acting under the Provider Agreement, assumed not only operational responsibilities but also constitutional obligations that the State owed in administering the federal program.

119. The USG owed Plaintiffs the constitutional right to refuse the INDs without penalty or pressure, which obligation was delegated to Washington, who in turn delegated that duty to Kaiser. This chain of delegated responsibilities and obligations preserves all constitutional protections for all potential recipients of the drugs available under the CDC Program.

120. Kaiser's discretionary authority under the CDC Program consisted of determining when, where, and to whom it would administer the INDs, but Kaiser was always under a ministerial duty to obtain an individual's legally effective informed consent.

121. Despite the CDC Program and applicable laws providing potential recipients with the right to refuse the drugs without penalty or pressure, Washington, owing Fourteenth Amendment obligations to all individuals, established a State-enforced custom whereby its recruited state actors could ignore their duties under the CDC Program and punish Plaintiffs should they refuse the EUA/PREP Act investigational drugs.

122. The use of official State policy to deny public benefits to Plaintiffs for the sole reason that they exercised their fundamental right and liberty interest under the CDC Program demonstrates a pervasive State-enforced custom subject to 42 U.S.C. §1983 remedy. See, *Adickes v. S. H. Kress & Co.*, 398 U.S. 144 (1970); *Peterson v. City of Greenville*, 373 U.S. 244 (1963);

Burton v. Wilmington Parking Authority, 365 U.S. 715 (1961); *Wickersham v. City of Columbia*, 481 F.3d 591 (8th Cir. 2007).

123. The State had a duty to ensure its licensed medical facilities did not promote a drug outside of its legal indication, which it refused to enforce under the CDC Program, establishing a custom that the drugs were not investigational but rather approved by the FDA, which is false.

124. The State had a duty to ensure that no person was placed under pressure to use drugs subject to 45 CFR Part 46, which the CDC Program was. However, the State turned a blind eye to its legal duties and allowed its recruited state actors, such as Kaiser, to mandate drugs that were undergoing clinical trials, labeled as investigational, and introduced into commerce only under emergency expanded access protocols of its employees, volunteers, vendors, and contractors, or whatever class of citizens the state actor mandated.[39]

125. Kaiser was a state actor when acting upon a pervasive State-enforced custom that deprived Plaintiffs of their Fourteenth Amendment rights, which is subject to §1983 remedy.

D. 42 U.S.C. §1983 Traceability – Causation of Injury or Damage

126. "A person, 'subjects' another to the deprivation of a constitutional right, within the meaning of section 1983, if he does an affirmative act, participates in another's affirmative acts, or omits to perform an act which he is legally required to do that causes the deprivation of which complaint is made." *Johnson v. Duffy*, 588 F.2d 740, 743 (9th Cir. 1978) citing *Sims v. Adams* (5th Cir. 1976).

127. Kaiser deprived Plaintiffs of a constitutional right because Kaiser either engaged in an affirmative act (i.e., established the unlawful IND Mandate), participated in another's affirmative act (i.e., enforced the IND Mandate), or omitted to perform an act (i.e., obtain

[39] Plaintiffs are not alleging that they were included in the clinical trials. Rather, Plaintiffs allege that they were offered the same drugs that were undergoing clinical trials and were not FDA-licensed according to their labeling.

Plaintiffs' legally effective informed consent) it was legally required to perform that caused Plaintiffs' injuries.

128. Kaiser Defendants, individually and/or collectively, signed the Provider Agreement, authorized Kaiser to perform for the State under the CDC Program, issued a policy violating Kaiser's promise to Washington, and/or failed to perform the duty of accepting Plaintiffs' refusal of the EUA/PREP Act investigational drugs without penalty or pressure.

129. Kaiser's mandate unconstitutionally conditioned Plaintiffs' fundamental rights, property rights, and liberty interests under the CDC Program and applicable laws upon seeking a religious or disability exemption and deprived Plaintiffs of their statutorily conferred right to refuse, which was an unconstitutional requirement because Kaiser deprived Plaintiffs' of their fundamental rights to refuse unwanted medical treatment and unwanted investigational drugs.

130. Kaiser's establishment and enforcement of the IND Mandate is the direct and proximate cause of Plaintiffs' injuries.

131. Kaiser required only persons refusing to inject the federally funded INDs to seek exemptions, engage in unwanted investigational medical testing, and/or be threatened with varieties of punishments, and Kaiser ultimately only terminated the careers of those who refused to surrender their Fourteenth Amendment rights guaranteed under the CDC Program.

132. The laws and legal precedents cited herein were clearly established at the time the IND Mandate was issued, and thus Kaiser knew or should have known that the foregoing actions violated Plaintiffs' constitutional and federal rights.

FIRST CAUSE OF ACTION
Fourteenth Amendment—Due Process Clause
Deprivation of Federal Benefits
42 U.S.C. §1983

133. Plaintiffs have a fundamental right and liberty interest in exercising their property rights under the CDC Program.

134. Kaiser, acting under color of law under the CDC Program, deprived Plaintiffs of these rights and interests afforded by the CDC Program.

135. The federal government's executive branch implemented the CDC Program and offered it to Plaintiffs under the authority and prerogative of the State as an emergency public function.

136. The federally funded CDC Program provided Plaintiffs with the opportunity to enjoy a federal benefit[40] provided or administered by Washington under its immunization cooperative agreement with the USG. Specifically, Plaintiffs' benefits included free medical counseling to learn of the drugs' risks, benefits, and alternatives and to be informed of their right to accept or refuse without costs, penalties, losing a benefit, and to enjoy the CDC Program's benefits without coming under pressure to use the CDC Program.

137. All drugs available under the CDC Program were authorized under the EUA Statute, and therefore, the option to accept or refuse was incorporated into the federally funded program as a property right held by Plaintiffs subject to the Fourteenth Amendment's due process clause.[41]

138. Kaiser placed Plaintiffs under threat of penalty should they refuse to participate in the CDC Program. When Plaintiffs refused, Kaiser deprived Plaintiffs' of their Fourteenth

[40] *Board of Regents of State Colleges v. Roth*, 408 U.S. 564 (1972)
[41] 21 U.S.C. §360bbb-3(e)(1)(A)(ii)(III)

Amendment rights by requiring them to seek exemptions, placing them under severe emotional duress fearing for their physical and financial safety, and ultimately terminating their careers.

139. Kaiser acted recklessly and with moral turpitude when mandating nonconsensual participation in the CDC Program, disregarding Plaintiffs' benefits under the CDC Program and their health and safety involving unlicensed investigational new drugs.

140. The CDC Program requires strict adherence to 21 U.S.C. §360bbb-3(e)(1)(A)(ii)(III)(the right to refuse), 45 C.F.R. Part 45 (Protection of Human Subjects), 10 U.S.C. §980 (Limitation on Use of Humans as Experimental Subjects), the Belmont Report, the Provider Agreement, EUAs, and the Fourteenth Amendment, all of which provide Plaintiffs with the fundamental right and liberty interest to refuse unwanted investigational drugs and medical treatment, and violations of those rights and interests are enforceable under §1983. *Health and Hospital Corporation of Marion Cty. v. Talevski*, 599 U.S. 166 (2023).

141. Additionally, 45 C.F.R. §46.122, 10 U.S.C. §980, and the CDC Program derive from spending legislation providing Plaintiffs with the right to refuse federally owned and funded INDs, which right is enforceable under §1983.

142. Kaiser, acting under color of law under the CDC Program and while acting pursuant to Washington's State-enforced custom of penalizing individuals who refused the drugs, engaged in a series of actions and/or omissions that deprived Plaintiffs' fundamental property right to enjoy a benefit, service, privilege, program, facility, or activity provided or administered by the United States under the State's authority.

143. Kaiser's transgressions include affirmative and direct individual and collective acts, participation in or facilitation of such actions by others, and/or failures to perform legally mandated duties.

144. Kaiser created an environment of undue pressure through threats and enforcement of unlawful penalties, depriving Plaintiffs' statutorily protected right to refuse.

145. This deprivation of a fundamental right guaranteed under the CDC Program constitutes a significant breach of Kaiser's legal obligations when acting under color of law and is a deprivation of the Plaintiffs' Fourteenth Amendment right to refuse the CDC Program's services, necessitating judicial remedy for the damages described below.

SECOND CAUSE OF ACTION
Fourteenth Amendment—Due Process Clause
Unwanted Use of EUA Drugs
42 U.S.C. §1983

146. The Due Process Clause of the Fourteenth Amendment guarantees that no State shall "deprive any person of life, liberty, or property without due process of law." U.S. CONST. amend. XIV, §1, cl. 3.

147. Plaintiffs have a fundamental right and liberty interest in exercising their property rights under the EUA Statute's right to refuse.

148. Kaiser acted pursuant to a State-enforced custom of penalizing individuals who refused the EUA drugs and thus acted under color of law when it issued an IND Mandate that deprived Plaintiffs of their fundamental right and liberty interest to refuse EUA drugs.

149. All drugs and devices available to Plaintiffs to comply with Kaiser's IND Mandate were introduced into commerce under emergency use authorization pursuant to 21 U.S.C. §360bbb-3 (the EUA Statute).

150. The right to be informed of the risks, benefits, and alternatives of an EUA product without financial costs and to be free from pressure when considering whether to receive the drug are property interests created by Congress for Plaintiffs' benefit.

151. Plaintiffs' fundamental right and liberty interest of bodily autonomy is further strengthened by Congress mandating that the HHS Secretary establish conditions under which Plaintiffs are informed of their unqualified right to accept or refuse an unlicensed emergency use drug without penalty or pressure.

152. Plaintiffs are entitled to proceed pursuant to 42 U.S.C. §1983 to seek redress for deprivation of their constitutional rights, property rights, and liberty interests under 21 U.S.C. §360bbb-3(e)(1)(A)(ii)(III) because the right to refuse is a right conferred upon individuals by the EUA Statute and because the EUA Statute does not contain a remedial scheme for violations of those rights. See *Health and Hospital Corporation of Marion Cty. v. Talevski*, 599 U.S. 166 (2023).[42]

153. The Supreme Court holds that legislation conferring an unambiguous right for Plaintiffs is a "legitimate claim of entitlement" as defined in *Board of Regents of State Colls. v. Roth*, 408 U.S. 564, 576-77, 92 S.Ct. 2701, 33 L.Ed.2d 548 (1972), *overruled in part and on other grounds in Paul v. Davis*, 424 U.S. 693, 96 S.Ct. 1155, 47 L.Ed.2d 405 (1976), elevating the right to a protected property interest subject to the Due Process Clause.

154. Congress authorized only the HHS Secretary to establish emergency expanded access protocols under the EUA Statute but restricted the Secretary from requiring nonconsensual use of EUA drugs, and his authority is nondelegable.

155. Kaiser is not the HHS Secretary and is not authorized to amend an EUA. Nor can it amend acts of Congress or misrepresent its authority when issuing the IND Mandate, establishing conditions conflicting with the EUA Statute, the EUA letters, and the required conditions mandated by Congress.

[42] Plaintiffs specifically allege that this action is not a private right of action to enforce the EUA Statute. Rather, this action is a §1983 action for the deprivation of Plaintiffs' conferred rights listed in the EUA Statute.

156. The requirement of all persons administering EUA drugs to ensure that Plaintiffs are informed of their right to accept or refuse under 21 U.S.C. §360bbb-3(e)(1)(A)(ii)(III) demonstrates that Congress unambiguously created a statutory entitlement specifically for "individuals" which is subject to the Due Process Clause and cannot be deprived outside of procedural due process.

157. Neither the State nor Kaiser can constitutionally mandate what Congress prohibits – nonconsensual use of EUA drugs.

158. The Supremacy Clause prohibits Kaiser from amending the EUA Statute and any EUA, which it did when establishing the IND Mandate punishing employees, contractors, and volunteers who refused the EUA drugs.

159. Kaiser, choosing to offer Plaintiffs an opportunity to use products authorized only for emergency use, was under a duty by the USG and Washington to ensure that:

> "All descriptive printed matter, advertising, and promotional material, relating to the use of the Pfizer-BioNTech COVID-19 Vaccine shall be consistent with the authorized labeling" and must "conspicuously [] state that: This product has not been approved or licensed by FDA, but has been authorized for emergency use by FDA, under an EUA to prevent Coronavirus."[43]

160. When issuing the IND Mandate, Kaiser failed to perform the governmental function of informing Plaintiffs that the drugs were investigational and not approved or licensed by the FDA for any indication, or of the drug's risks, benefits, and alternatives, or of their right to accept or refuse them without penalty or pressure, or accept their freely given consent, all as required by the CDC Program and applicable federal laws.

[43] See Exhibit C, August 23, 2021 EUA Letter, Sections X and Y

161. Despite not being empowered to amend any EUA, Kaiser did so when mandating nonconsensual use of EUA drugs and requiring Plaintiffs to seek a medical or religious exemption despite Plaintiffs already having the right to refuse the EUA products, thereby violating Plaintiffs' Fourteenth Amendment due process rights.

162. Kaiser is not Congress, and it is not authorized to amend the Food, Drug, and Cosmetic Act ("FDCA") to establish a prohibited act under 21 U.S.C. §331 of refusing a drug not licensed under 21 U.S.C. §355, and only offered under 21 U.S.C. §360bbb-3, which Kaisesr did when establishing and enforcing the IND Mandate, nor can Kaiser amend the EUA Statute to punish the option to refuse by creating a penalty under 21 U.S.C. §333.

163. The "option" is not subject to Kaiser's authority; rather, Kaiser is obligated to protect Plaintiffs' property rights under the statute on behalf of the State, which Kaiser failed to do when establishing and enforcing the IND Mandate.

164. The drugs under Kaiser's IND Mandate were listed as countermeasures under the PREP Act, which expressly preempted Kaiser from issuing the official policy.

165. The PREP Act states that Kaiser, acting under color of law, cannot establish or continue in effect with any legal requirement relating to "the covered countermeasure, or to any matter included in a requirement applicable to the covered countermeasure under this section or any other provision of this chapter, or under the **Federal Food, Drug, and Cosmetic Act**." ("FDCA")[44] (emphasis added). (42 U.S.C. §247d-6d(b)(8))

166. 21 U.S.C. §360bbb-3(e)(1)(A)(ii)(III) is under the FDCA and thus subject to the PREP Act's express preemption legal requirement.

[44] 21 U.S.C. §301 *et seq*.

167. Kaiser was at all times material preempted from establishing a legal requirement conflicting with the option to refuse, which requirement nullified the constitutional authority of Congress to completely prohibit the nonconsensual use of federally owned EUA drugs.

168. Kaiser willfully assumed the role as "vaccination provider" under any EUA requiring the "Organization"[45], as a state actor, to inform Plaintiffs of their right to refuse, which Kaiser failed to perform by depriving that right from Plaintiffs when punishing them for exercising their right to refuse.

169. Kaiser, acting under color of law, engaged in a series of actions and/or omissions that deprived Plaintiffs' fundamental right to refuse EUA investigational drugs without penalty or pressure.

170. Kaiser's transgressions include affirmative and direct individual and collective acts, participation in or facilitation of such acts by others, and/or failures to perform legally mandated duties.

171. Kaiser created an environment of undue pressure through threats and enforcement of unlawful penalties, depriving Plaintiffs' statutorily protected right to refuse.

172. This deprivation of a fundamental right, guaranteed under the EUA Statute, constitutes a significant breach of Kaiser's legal obligations when acting under color of law and a direct assault on Plaintiffs' Fourteenth Amendment property right to refuse EUA investigational drugs funded by the federal government, necessitating judicial remedy for the damages described below.

[45] The "Organization" is the person required to sign the Provider Agreement and thus, Kaiser, as the "Organization," agreed to execute the conditions of authorization outlined under any EUA as required under "12(a)" of the Provider Agreement.

THIRD CAUSE OF ACTION
Fourteenth Amendment—Due Process Clause
Unwanted PREP Act Countermeasure
42 U.S.C. §1983

173. Plaintiffs have a fundamental right and liberty interest in exercising their right to refuse PREP Act countermeasures involving the Fourteenth Amendment's due process clause, which Kaiser's actions deprived them of.

174. Kaiser, acting under color of law relative to the PREP Act countermeasures under the CDC Program, deprived Plaintiffs of those rights and interests.

175. Kaiser acted pursuant to a State-enforced custom of penalizing individuals who refused the PREP Act countermeasures and thus acted under color of law when it issued an IND Mandate that deprived Plaintiffs of their fundamental right and liberty interest to refuse PREP Act countermeasures.

176. All drugs and devices available to Plaintiffs to comply with Kaiser's IND Mandate were listed as countermeasures under 42 U.S.C. §247d-6d ("PREP Act").

177. The PREP Act significantly impacts Plaintiffs' fundamental legal rights, particularly in the context of the Fourteenth Amendment's Due Process Clause. This legislation places considerable restrictions on individuals' ability to pursue various common-law causes of action, including product liability claims, medical malpractice suits, fraud allegations, and battery charges. Moreover, the Act limits Plaintiffs' capacity to seek tort remedies for bodily harm inflicted by other members of society if related to PREP Act countermeasures, and constrains their right to be made whole for financial damages and emotional distress. These restrictions deprive Plaintiffs' fundamental rights under the Due Process Clause of the Fourteenth Amendment.

178. It is crucial to note that the Fourteenth Amendment sets a stringent standard for due process rights. According to this constitutional provision, if even a single due process right is

denied to Plaintiffs under the PREP Act, it triggers the fundamental protections enshrined in the Fourteenth Amendment's Due Process Clause. This interpretation underscores the gravity of any infringement on individual rights, even if it occurs in isolation, and clearly demonstrates why Congress requires the HHS Secretary to "ensure…that potential participants are educated with respect to …the voluntary nature of the program…" 42 U.S.C. §247d-6e(c)

179. The PREP Act itself does not deprive a person of their Fourteenth Amendment rights since that right must be voluntarily surrendered under the Act. It was Kaiser's IND Mandate issued pursuant to a State-enforced custom, and Kaiser's threat and enforcement of penalty, that deprived Plaintiffs of their fundamental rights by penalizing the option of refusing PREP Act countermeasures (i.e., Pfizer-BioNTech COVID-19 Vaccine and masking devices), thus penalizing Plaintiffs for refusing to surrender their fundamental due process rights under the Fourteenth Amendment.

180. In *Logan v. Zimmerman Brush Co*., 455 U.S. 422 (1982), the Supreme Court held,

> The hallmark of property is an individual entitlement grounded in state law, which cannot be removed except "for cause," and appellant's right shares this characteristic.
>
> * * *
>
> The first question, we believe, was affirmatively settled by the *Mullane* case itself, where the Court held that a cause of action is a species of property protected by the Fourteenth Amendment's Due Process Clause.

See also, Tulsa Prof. Collection Svcs. v. Pope, 485 U.S. 478 (1988); *Phillips Petroleum Co. v. Shutts*, 472 U.S. 797 (1985).

181. The Act's significant forfeiture of a person's due process rights must result from voluntary surrender, not mandatory compulsion. Congress unambiguously preempted Washington and Kaiser from interfering with that due process right, stating

> "During the effective period of a declaration under subsection (b)…no State or political subdivision of a State may establish, enforce, or continue in effect with respect to a covered counter-measure any provision of law or legal requirement that— (A) is different from, or is in conflict with, any requirement applicable under this section; and (B) relates to the…administration…of the covered countermeasure, or to any matter included in a requirement applicable to the covered countermeasure under this section or any other provision of this chapter, or under the **Federal Food, Drug, and Cosmetic Act**." ("FDCA")[46] (emphasis added). (42 U.S.C. §247d-6d(b)(8))

182. Washington's State-enforced custom of penalizing individuals who refused the PREP Act countermeasures and EUA drugs is a legal requirement that is "different from, or is in conflict with" the voluntary nature of a PREP Act program and the right to refuse under the EUA Statute.

183. Kaiser, as a state actor under the CDC Program and while acting pursuant to a State-enforced custom of penalizing individuals who refused the PREP Act countermeasures, is not authorized to constitutionally mandate that Plaintiffs surrender their fundamental right to due process as required under the PREP Act. Therefore, the IND Mandate and its enforcement violated Plaintiffs' Fourteenth Amendment substantive due process rights when Kaiser punished Plaintiffs for refusing to surrender that right without providing Plaintiffs with a hearing before an impartial decision maker.

184. Under the PREP Act's express preemption language, the right to refuse (21 U.S.C. §360bbb-3(e)(1)(A)(ii)(III)) is incorporated into the PREP act because it is a "requirement applicable to the covered countermeasure" under the FDCA and is a property interest enforceable under §1983. *Health and Hospital Corporation of Marion Cty. v. Talevski*, 599 U.S. 166 (2023).

[46] 21 U.S.C. §301 *et seq*.

185. Moreover, Kaiser's requirement that Plaintiffs use a PREP Act countermeasure is an unconstitutional condition requiring Plaintiffs to surrender their fundamental right to due process (i.e., access to the courts to file common law tort actions in the event of injury) guaranteed to them under the Fourteenth Amendment.

186. Despite the Supreme Court holding that a public entity cannot "produce a result which it could not command directly,"[47] Washington used Kaiser to accomplish a result that the State could not command directly: involuntary surrender of Plaintiffs' Fourteenth Amendment due process rights to bring common law causes of action should they incur injury from the PREP Act countermeasure.

187. Therefore, neither Washington nor Kaiser can constitutionally mandate that Plaintiffs use a PREP Act countermeasure as a condition of enjoying a public benefit (i.e., using their State-issued healthcare licenses).

188. The PREP Act expressly preempts interference in Plaintiffs' option to accept or refuse under the EUA Statute.

189. Kaiser, acting under color of law under the CDC Program and while acting pursuant to Washington's State-enforced custom of penalizing individuals who refused the PREP Act countermeasures, engaged in a series of actions and/or omissions that deprived Plaintiffs of their fundamental right to refuse PREP Act countermeasures without penalty or pressure.

190. Kaiser's transgressions include affirmative and direct individual and collective acts, participation in or facilitation of such actions by others, and/or failures to perform legally mandated duties.

[47] *Perry v. Sindermann*, 408 U.S. 593 (1972) quoting *Speiser v. Randall*, 357 U.S. 513 (1958)

191. Kaiser created an environment of undue pressure through threats and enforcement of unlawful penalties, depriving Plaintiffs' statutorily protected right to refuse.

192. This deprivation of a fundamental right to refuse, guaranteed under the PREP Act and its express preemption language, constitutes a significant breach of Kaiser's legal obligations when acting under color of law and is a deprivation of Plaintiffs' Fourteenth Amendment right to refuse PREP Act countermeasures, necessitating judicial remedy for the damages described below.

FOURTH CAUSE OF ACTION
Fourteenth Amendment—Due Process Clause
Unwanted Investigational Drugs and Unwanted Medical Treatment
42 U.S.C. §1983

193. The Due Process Clause of the Fourteenth Amendment guarantees that no State shall "deprive any person of life, liberty, or property without due process of law." U.S. CONST. amend. XIV, §1, cl. 3.

194. Plaintiffs have a fundamental right and liberty interest to refuse unwanted investigational drugs and unwanted medical treatments.[48]

195. Kaiser acted pursuant to a State-enforced custom of penalizing individuals who refused the investigational drugs and thus acted under color of law when it issued an IND Mandate that deprived Plaintiffs of their fundamental right and liberty interest to refuse unwanted investigational drugs and unwanted medical treatments.

196. Kaiser's *discretionary* authority relating to Plaintiffs was limited to presenting the offer to be administered federally funded investigational drugs. Kaiser was under a *ministerial* duty to accept Plaintiffs' freely given consent pursuant to its FWA.

[48] *Cruzan, supra; Albright, supra*; *Washington v. Glucksberg*, *supra*; *Missouri v. McNeely*, 569 U.S. 141, 148 (2013).

197. Kaiser's enactment and enforcement of the IND Mandate deprived Plaintiffs of their fundamental right to give their legally effective informed consent.

198. The right to refuse unwanted investigational drugs is "deeply rooted" and "implicit in the concept of ordered liberty," such that "neither liberty nor justice would exist if they were sacrificed." *Washington v. Glucksberg*, *supra*.

199. Kaiser recklessly and with willful and wanton disregard for Plaintiffs' health,[49] safety, and legal rights, failed to perform the ministerial function of obtaining Plaintiffs' legally effective informed consent; rather, Kaiser punished Plaintiffs when they exercised their right to refuse, which conduct was outside the scope of Kaiser's authority.

200. Kaiser, acting under color of law, engaged in a series of actions and/or omissions that deprived Plaintiffs of their fundamental right to refuse investigational drugs and unwanted medical treatments without penalty or pressure.

201. Kaiser's transgressions include affirmative and direct individual and collective acts, participation in or facilitation of such acts by others, and/or failure to perform legally mandated duties.

202. Kaiser created an environment of undue pressure through threats and enforcement of unlawful penalties, depriving Plaintiffs of their constitutionally protected right to refuse investigational drugs and unwanted medical treatments.

203. This deprivation of a fundamental right, guaranteed under the aforementioned federal statutes and constitutional provisions, constitutes a significant breach of Kaiser's legal obligations when acting under color of law and is a direct assault on Plaintiffs' Fourteenth

[49] VAERS reported 1,562,008 entries from December 2020 through May 26, 2023, including 35,272 deaths (1.6 per hour) and 263,462 (12.11 per hour) severe injuries for the new and unvetted mRNA drugs listed under Kaiser's mandate.

Amendment right to refuse unwanted investigational drugs and unwanted medical treatments, necessitating judicial remedy for the damages described below.

FIFTH CAUSE OF ACTION
Fourteenth Amendment—Equal Protection Clause
Deprivation of Equal Protection Rights
42 U.S.C. §1983

204. The Equal Protection Clause of the Fourteenth Amendment, U.S. CONST. amend. XIV, §1, cl. 4, guarantees Plaintiffs equal protection of the laws, "which is essentially a direction that all persons similarly situated should be treated alike." *City of Cleburne v. Cleburne Living Ctr.*, 473 U.S. 432, 439 (1985).

205. Plaintiffs have a fundamental right and liberty interest in being treated equally before the law.

206. Kaiser was a state actor under the CDC Program and acted pursuant to a State-enforced custom of penalizing individuals who refused the EUA drugs and thus acted under color of law when it issued an IND Mandate that deprived Plaintiffs of their fundamental right and liberty interest in being treated equally before the law.

207. Kaiser deprived Plaintiffs of those rights and interests.

208. When a government action resulting in an equal protection claim interferes with the exercise of a fundamental right, the government must satisfy strict scrutiny. *Nat'l Rifle Ass'n of Am., Inc. v. McCraw*, 719 F.3d 338, 350 (5th Cir. 2013).

209. Plaintiffs are similarly situated to other citizens who were given the same opportunity to be injected with the federally funded INDs.

210. Alternatively, Plaintiffs assert a "class of one" equal protection claim. They are licensed healthcare workers similarly situated as all other healthcare workers in Washington.

211. Plaintiffs were denied the equal protection of the laws when Kaiser punished Plaintiffs' option to refuse under the EUA Statute (21 U.S.C. §360bbb-3(e)(1)(A)(ii)(III)), CDC Program, and 45 C.F.R. §46.116, but did not punish other healthcare workers choosing the equal option to accept.

212. Plaintiffs were denied the equal protection of the laws when Kaiser punished their right to refuse the INDs but did not punish other healthcare workers who chose to accept the INDs.

213. Plaintiffs were denied equal protection of the laws when Kaiser punished Plaintiffs who chose not to use the federally funded CDC Program but did not punish other healthcare workers who chose to participate.

214. Kaiser knew that persons acting on behalf of the USG as vaccination providers under the CDC Program were required to ensure that no person was under pressure to use the INDs and was required to ensure that the options to accept and to refuse were treated equally without discrimination against one option.

215. Kaiser, acting under color of law under the CDC Program and while acting pursuant to a State-enforced custom of penalizing individuals who refused the drugs, engaged in a series of actions and/or omissions that unlawfully infringed upon Plaintiffs' fundamental Fourteenth Amendment right to Equal Protection of Laws described above.

216. Kaiser's transgressions include affirmative and direct individual and collective acts, participation in or facilitation of such actions by others, and/or failures to perform legally mandated duties.

217. Kaiser created an environment of undue pressure through threats and enforcement of unlawful penalties, discriminating against Plaintiffs for their statutorily protected choice to refuse.

218. This deprivation of the Fourteenth Amendment Equal Protection of Laws constitutes a significant breach of Kaiser's constitutional obligations when acting under color of law. They are a direct assault on Plaintiffs' Fourteenth Amendment rights, necessitating judicial remedy for the damages described below.

SIXTH CAUSE OF ACTION
Fourteenth Amendment—Right To Privacy
Deprivation of Right to Privacy
42 U.S.C. §1983

219. The Fourteenth Amendment provides Plaintiffs with a fundamental right and liberty interest in the right of privacy from unwanted, unwarranted, and unjustified governmental intrusion. *Griswold v. Connecticut*, 381 U.S. 479, 85 S.Ct. 1678, 14 L.Ed.2d 510 (1965).

220. Plaintiffs have a fundamental right of privacy.

221. Kaiser was a state actor under the CDC Program and acted pursuant to a State-enforced custom of penalizing individuals who refused the EUA drugs [ACCURATE?] and thus acted under color of law when it issued an IND Mandate that deprived Plaintiffs of their fundamental right to privacy.

222. Kaiser, acting under color of law, deprived Plaintiffs of that right.

223. Plaintiffs have a legally protected interest in their bodily integrity and whether to receive investigational or non-investigational medical treatments.

224. Moreover, Plaintiffs have the fundamental right to refuse public disclosure of their private health information as required by the CDC Program. Specifically, the CDC Program required Plaintiffs to disclose their private identifiable and health information to the authorized vaccination provider that it, the USG, and the drugs' manufacturer could use for unknown purposes and length of time. Kaiser is not authorized to condition the right to enjoy the benefits of a federal

program they conduct on behalf of Washington upon Plaintiffs' publicly disclosing their private health information.

225. Kaiser, acting under color of law, continually invaded Plaintiffs' privacy by demanding that Plaintiffs inform Kaiser when, where, and from whom Plaintiffs were or were not injected with investigational drugs.

226. Plaintiffs have a fundamental right and liberty interest in refusing to become human subjects in the federally funded research activities required under the CDC Program. Specifically, the CDC Program required the drug manufacturer, Washington, and the State's vaccination providers to monitor and report adverse events that individuals encounter with the investigational drugs which constitute becoming a human subject pursuant to 45 CFR §§46.102(e)(1), 46.102(e)(5), and 46.102(l).

227. Plaintiffs possess a fundamental right and liberty interest in refusing the collection, study, sharing, and usage of data concerning their involvement with the CDC Program and any adverse reactions to the Investigational New Drugs (INDs). This privacy interest extends to protecting their information from being handled by unspecified individuals for undisclosed purposes and for an indefinite period, as mandated under the CDC Program.

228. Washington used Kaiser to invade Plaintiffs' right to privacy from governmental intrusion[50] when it allowed Kaiser to engage in its State-enforced custom to establish and enforce the IND Mandate.

229. Kaiser had no authority to invade the privacy of Plaintiffs when they were considering whether to receive investigational drugs or unwanted medical treatments; nor did Kaiser have authority to mandate that Plaintiffs disclose such private health information under

[50] *Griswold v. Connecticut, supra*.

threat of penalty. This form of governmental invasion by Washington through its state actors is precisely what the Supreme Court addressed in *Griswold*, *supra*.

230. Kaiser has no authority to compel Plaintiffs to subject themselves to federally funded research activities and assume greater health risks than they would be subjected to by contracting the virus that Kaiser's mandate purported to prevent.

231. Kaiser has no authority to legally mandate disclosure of Plaintiffs' private health information to be used for undisclosed legal purposes.

232. Kaiser, acting under color of law, engaged in a series of actions and/or omissions that unlawfully infringed upon Plaintiffs' fundamental Fourteenth Amendment right to Privacy as described above.

233. Kaiser's transgressions include affirmative and direct individual acts, participation in or facilitation of such actions by others, and/or failures to perform legally mandated duties.

234. Kaiser created an environment of undue pressure through threats and enforcement of unlawful penalties, depriving Plaintiffs' statutorily protected right to enjoy Fourteenth Amendment Privacy protections.

235. This deprivation of the Fourteenth Amendment right to privacy constitutes a significant breach of Kaiser's constitutional obligations when acting under color of law. They are a direct assault on Plaintiffs' Fourteenth Amendment rights, necessitating judicial remedy for the damages described below.

VII. Damages Recoverable and Demanded

236. As a direct and proximate result of the Kaiser's unreasonable and unlawful actions, Plaintiffs have suffered past damages and will suffer future damages, both compensatory and

general, including, but not limited to, front and back pay; loss of benefits; loss of accumulated sick pay; loss of retirement accounts; lost earnings on retirement funds; vacation time, compensatory time, and paid time off; negative tax consequences (in the event of a lump sum award), including related accountant fees; attorney's fees; emotional distress; mental, psychological and physical harm; loss of income; loss of enjoyment of life; for which Kaiser is liable in compensatory, legal, equitable, and all other damages that this Court deems necessary and proper.

237. When a defendant's behavior reaches a sufficient threshold, which occurred in this case regarding Kaiser Defendants, in their individual capacities, punitive damages are recoverable in §1983 cases. *Smith v. Wade*, 461 U.S. 30 (1983)

238. Because Kaiser's actions were intentional, willful, reckless, with callous indifference to the Plaintiffs' federally protected rights, and/or motivated by evil motive or intent, Plaintiffs are entitled to, and hereby demand, an award of punitive damages against Kaiser Defendants in their individual capacities in an amount sufficient to deter them, individually, from repeating their unconstitutional actions. *Smith v. Wade*, 461 U.S. 30 (1983)

VIII. Jury Trial Demand

239. Plaintiffs are entitled to, and hereby demand, a trial by jury on all issues of fact herein.

WHEREFORE, Plaintiffs pray that Defendants be served with a copy of this Complaint and be cited to appear and answer same, and after due proceedings are had, including a trial by jury, there be judgment herein against Defendants awarding Plaintiffs all damages claimed herein, plus legal interest, costs, expert fees, attorney's fees, and all other relief determined to be just and equitable by this Court.

Respectfully submitted,

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